

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

SUNG KIM, et al.,
Plaintiffs,
v.
ALLAKOS INC., et al.,
Defendants.

Case No. [20-cv-01720-JSW](#)

**ORDER GRANTING MOTION TO
DISMISS AND DENYING
PLAINTIFF'S REQUEST TO RE-OPEN
LEAD PLAINTIFF SELECTION
PROCESS**

Re: Dkt. Nos. 46, 59

This matter comes before the Court on consideration of Defendants' motion to dismiss Plaintiffs' Second Amended Complaint ("SAC"). The Court has considered the parties' papers, including Plaintiffs' sur-reply and Defendants' response, relevant legal authority, and the record in this case. For the reasons that follow, the Court GRANTS the motion to dismiss, and DENIES Plaintiffs' motion for leave to reopen the Lead Plaintiff selection process to further amend their complaint.

BACKGROUND

The Court summarized the facts in its Order granting Defendants' motion to dismiss the first amended complaint ("FAC"), and it will not repeat them in detail here. (*See* Dkt. No. 40.) In brief, Allakos is a clinical stage biopharmaceutical company that is focused on a single drug, AK002, which it is developing to treat eosinophil and mast related cell diseases, including eosinophilic gastritis ("EG") and eosinophilic gastroenteritis ("EGE"). During 2018 and the first half of 2019, Allakos conducted a Phase 2 clinical trial, called the ENIGMA Trial, which tested AK002 on EG and EGE patients for safety and effectiveness. Plaintiffs sought to represent a class of persons who purchased Allakos stock between March 14, 2019 and December 17, 2019, based

1 on statements made in connection with the Phase 2 trial.

2 The Court concluded Plaintiffs failed to allege that any of the challenged statements were
3 misleading but granted Plaintiffs leave to amend. Plaintiffs amended to expand the Class Period
4 to encompass stock purchases made between March 14, 2019 and December 21, 2021. They also
5 challenge two statements that Defendant Tomasi made on September 10, 2021 during a Morgan
6 Stanley Healthcare Conference.

7 In response to a request to “walk-through” data from the Phase 2 trial and to explain “what
8 drove you to sort of move into the Phase 3,” Tomasi stated that the Phase 2 trial “looked at
9 placebo low dose of [AK002] and then a high dose of [AK002],” with about 20 patients per arm.
10 (SAC, Ex. 5 at 4.) Tomasi stated that Allakos saw a “93% or 95% reduction in eosinophil counts
11 and tissue on the active arm relative, I believe to like a 10% perhaps increase in the placebo
12 group.” (*Id.* at 4-5.) Tomasi then spoke about the results of symptom reduction in both doses and
13 the placebo group, which were “quite notable” and formed the basis of the plan to move to Phase
14 3. (*Id.* at 5.)

15 Tomasi then stated that “[t]he Phase 3 study is identical with regards to patient
16 population that we’re [en]rolling. Chief difference is that we’re focusing [on] the high-dose
17 group given greater efficacy that we saw in Phase 2[. T]hat study is 80 patients per arm instead of
18 being 20 patients per arm, given the strong p-values that we saw in Phase 2, the phase 3 study will
19 power on its end points.” (SAC ¶ 149 (emphasis in original to designate challenged statement);
20 see also SAC, Ex. 5 at 5.) The Court will refer to the statement in bold as the “Enrollment
21 Statement.”

22 Tomasi also was asked what he thought the key risk to a successful Phase 3 study would
23 be. Tomasi reiterated the Phase 2 study data was very positive and reiterated the small size of that
24 study. He then stated:

25 As a result ... [the] thing we want to do is make sure that we were
26 running essentially the same experiment. And to do that, we want to
27 make sure we were looking at similar or same endpoints which I think
28 partly where we are [*sic*]. And then probably the most important thing
is to make sure that we enrolled the same patient population so that
you’re really – you have the greatest chance to have to repeat the
effect seen[.]

And so our focus is really making sure that we have the same enrollment criteria which we do. And then as making sure that we have the same type of demographics going into the phase 3 study, making sure that the baseline TSS [is] in the same or similar place. And the Phase 3 study as it was in Phase 2 and, and yeah the stud[y is] fully enrolled now. So I can say that these two things are true. ***So we do have a very similar patient population in phase 3 as we do in phase 2***, so I think that was really probably the most thing that, the most important thing that was in our control.

(SAC ¶ 150 (emphasis in original to designate challenged statement); *see also* SAC, Ex. 5 at 6.)

The Court will refer to the bold statement as the “Population Statement.”

In February 2022, Allakos announced that the Phase 3 population differed from the Phase 2 population in terms of diagnostic history and baseline eosinophil and IgE levels. (*Id.* ¶¶ 16, 150.) The Court will address additional facts as necessary in the analysis.

ANALYSIS

A. The Court Grants the Motion to Dismiss as Unopposed.

Plaintiffs did not make substantive amendments their claims regarding the Phase 2 trial, and they state they included those allegations to preserve them for appeal. Based on the Court’s previous ruling, Plaintiffs again fail to state a claim regarding the Phase 2 trial.

Plaintiffs also have failed to amend to include any additional statements by individual defendants other than Tomasi, and the newly challenged statements post-date each named Plaintiff’s purchase of shares in Allakos. Plaintiffs concede that, as a result, they cannot maintain claims based on those statements. *See, e.g., Hanon v. Dataproducts Corp.*, 976 F.2d 497, 501 & n.3 (9th Cir. 1988) (granting summary judgment and concluding it was unnecessary to determine if a statement was “misleading because it was issued after [plaintiff] bought his stock and thus could not have affected his stock’s April 14, 1989 market price or his decision to buy on that date,” where there was no evidence the plaintiff relied on post-purchase statement in holding on to the stock); *Kelly v. Electronic Arts*, 71 F. Supp. 3d 1061, 1069-70 (N.D. Cal. 2014) (dismissing claims based on post-purchase statements, with leave to amend to substitute new plaintiffs).

Accordingly, the Court GRANTS Defendants’ motion. The Court dismisses all claims based on the Phase 2 trial with prejudice. The Court now must consider whether it should, over

Defendants' opposition, grant Plaintiffs the opportunity to find a new lead plaintiff, as they have requested.

B. The Court Denies Plaintiffs Leave to Amend to Add a New Lead Plaintiff.

In general, if the allegations are insufficient to state a claim, a court should grant leave to amend. *See, e.g. Reddy v. Litton Indus., Inc.*, 912 F.2d 291, 296 (9th Cir. 1990). The five factors commonly used to evaluate the propriety amendment are: (1) undue delay, (2) bad faith or dilatory motive on the part of the movant, (3) repeated failure of previous amendments, (4) undue prejudice to the opposing party, and (5) futility of the amendment. *See Foman v. Davis*, 371 U.S. 178, 182 (1962). "[T]he consideration of prejudice to the opposing party...carries the greatest weight." *Eminence Capital, LLC v. Aspeon, Inc.*, 316 F.3d 1048, 1052 (9th Cir.2003). Absent prejudice or a "strong showing" of any other *Foman* factor, there is a presumption in favor of granting leave to amend. *Id.*

Defendants do not articulate any particular prejudice they would suffer if the Court gave leave to amend. The age of the case cannot be attributed solely to Plaintiffs because of the time the Court had Defendants' motion to dismiss the FAC under submission. Those factors weigh in favor of giving Plaintiffs an opportunity to amend to name a new Lead Plaintiff. If the Court grants Plaintiffs leave to amend, it would be the fourth iteration of the complaint, and the Court has greater discretion in evaluating whether to give leave to amend in such circumstances. *See Salameh v. Tarsadia Hotel*, 726 F.3d 1124, 1133 (9th Cir. 2013).

The fact that the newly challenged statements clearly post-date the dates on which Plaintiffs purchased their shares suggests a dilatory motive. In addition, Plaintiffs have not identified any particular individuals or entities who could be substituted in as Lead Plaintiff, and when Kim originally filed the complaint there were no other candidates for that role. The Court concludes each of these facts weigh against granting leave to amend. Therefore, the Court turns to whether amendment would be futile.

1. Falsity.

Defendants argue that Plaintiffs fail to allege that either of the newly alleged statements are false. A statement is misleading "if it would give a reasonable investor the impression of a state of

1 affairs that differs in a material way from the one that actually exists.” *In re Cutera Sec. Litig.*,
2 610 F.3d 1103, 1109 (9th Cir. 2010) (internal citation and quotation omitted).

3 Plaintiffs argue the Enrollment Statement is misleading based on the information Allakos
4 disclosed in February 2022. Defendants argue that, when the statement is viewed in context,
5 Tomasi was not referring to the differences in the diagnostic history or in baseline levels of
6 eosinophils and IgE. The Court agrees that, when viewed in context, Tomasi was emphasizing the
7 structure and results in the Phase 2 trial and the change in the size for Phase 3. In that context, the
8 statement cannot be read to refer to anything other than the enrollment criteria.

9 However, the Court concludes Plaintiffs have sufficiently alleged that the Population
10 Statement is misleading. Defendants argue that when Tomasi said that the patient population was
11 similar, he was referencing to patients’ TSS level and the enrollment criteria. Prior to making the
12 challenged statement, Tomasi said that he could say “two things are true.” (SAC ¶ 150.)
13 Plaintiffs argue that those “two things” could refer to patient demographics generally and the TSS
14 level specifically. The Court agrees that Plaintiffs’ reading of Tomasi’s statement is plausible and
15 that “demographics” could be construed to include diagnostic history and the levels of eosinophils
16 and IgE.

17 Accordingly, the Court concludes Plaintiffs alleged at least one misleading statement,
18 which weighs in favor of granting Plaintiffs leave to amend to include a new Lead Plaintiff.

19 **2. Scier.**

20 Defendants also argue that Plaintiffs do not plead a “strong” inference of scier. *See* 15
21 U.S.C. § 78u-4(b)(2)(A). The scier inquiry is “inherently comparative,” and the Court must
22 “consider plausible nonculpable explanations for the defendant’s conduct as well as inferences
23 favoring the plaintiff.” *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 323-24 (2007)
24 (“*Tellabs*”). The Court also must adopt a holistic view and “a practical and common-sense
25 perspective.” *S. Ferry LP, No. 2 v. Killinger*, 542 F.3d 776, 784 (9th Cir. 2008). “A complaint
26 will survive, ... only if a reasonable person would deem the inference of scier cogent and at
27 least as compelling as any opposing inference one would draw from the facts alleged.” *Tellabs*,
28 551 U.S. at 324.

1 To act with scienter, Tomasi must have made the allegedly misleading statement “either
2 intentionally or with deliberate recklessness.” *Zucco Partners, LLC v. Digimarc Corp.*, 552 F.3d
3 981, 991 (9th Cir. 2009). Plaintiffs argue the allegations demonstrate Tomasi was deliberately
4 reckless, *i.e.*, that he acted with “some degree of intentional or conscious misconduct.” *S. Ferry*,
5 542 F.3d at 782. “[A]n actor is [deliberately] reckless if he had reasonable grounds to believe
6 material facts existed that were misstated or omitted, but nonetheless failed to obtain and disclose
7 such facts although he could have done so without extraordinary effort.” *In re Oracle Corp. Sec.*
8 *Litig.*, 627 F.3d 376, 390 (9th Cir. 2010).

9 The parties agree that the differences between the Phase 2 and Phase 3 patient populations
10 contributed to the lack of success for the Phase 3 trial. Plaintiffs argue that “[t]he entire purpose
11 of Tomasi[’s] comments was to reassure investors that the patient populations were the same so
12 that they would believe that Phase 3 would be successful.” (Opp. Br. at 14:23-25.) Plaintiffs
13 *allege*, however, that Tomasi’s motive was to conceal the differences between Phase 2 and Phase
14 3 patients because that would have undermined the results of a Prevalence Study, which suggested
15 there was a much larger market for AK002 than Allakos originally anticipated. (SAC ¶¶ 174-
16 175.) One of the alleged differences between Phase 2 and Phase 3 patients is that Phase 3 patients
17 had milder symptoms. The Court agrees with Defendants that the facts alleged, if true, would
18 suggest that Tomasi would have had a motive to highlight those differences. *Cf. Nguyen v.*
19 *Endologix, Inc.*, 962 F.3d 405 (9th Cir. 2020) (finding plaintiffs’ allegations of motive did not
20 support scienter because it made no sense for the defendants “to keep the stock price high for a
21 time and then face” an inevitable fallout when intractable problem was discovered).

22 Plaintiffs rely, in part, on the fact that Tomasi was President and COO of Allakos, as well
23 as the fact the company publicly stated it was “highly dependent” on him, to show he would have
24 had access to information about the Phase 3 patient population. (SAC ¶ 173.) A plaintiff may rely
25 on the “core operations” inference to plead scienter, but the Court concludes the allegations here
26 are insufficient to make it one of the “exceedingly rare” cases where the core operations inference
27 alone would be sufficient to plead scienter. *S. Ferry*, 542 F.3d at 785 n.3; *see also Berson v.*
28 *Applied Signal Tech., Inc.*, 527 F.3d 982, 988-89 (9th Cir. 2008) (finding core operations alone

1 established scienter where individual defendants were involved in “day to day operations” of
2 defendant company and the magnitude of the loss made it “absurd to suggest” that the defendants
3 were not aware of those facts).

4 A plaintiff also can establish scienter under a core operations theory when they include
5 “detailed and specific allegations about management’s exposure to factual information within the
6 company.” *S. Ferry*, 542 F.3d at 785. In contrast, “[g]eneral allegations of defendants hands-on
7 management style, their interaction with other officers and employees, their attendance at monthly
8 meetings, and their receipt of unspecified weekly or monthly reports,” are not sufficient to
9 establish scienter. *In re Daou Sys., Inc.*, 411 F.3d 1006, 1022 (9th Cir. 2005) (internal
10 quotations and citations omitted); *cf. Lopes v. Fitbit, Inc.*, No. 18-cv-665-JST, 2020 WL 1465932,
11 at *11 (N.D. Cal. Mar. 23, 2020) (finding “generalities about management’s access to data” was
12 insufficient and did not provide the “who, what, where, when, and how” each defendant gained
13 access to the relevant information) (internal quotations and citations omitted). There is no serious
14 dispute that Tomasi was aware of the results of the Prevalence Study and that he was familiar with
15 the Phase 3 trial. Accepting Plaintiffs’ interpretation of the Population Statement as true, it is
16 reasonable to infer that Tomasi had information about patient characteristics when he said the
17 patient population in the Phase 3 trial was similar to Phase 2. That inference is supported by
18 Plaintiffs’ allegations in paragraphs 124 and 125.

19 Plaintiffs also rely on Tomasi’s stock sales to support their allegations of scienter.
20 “[I]nsider trading is suspicious only when it is dramatically out of line with prior trading practices
21 at times calculated to maximize the personal benefit from undisclosed inside information.” *In re*
22 *Silicon Graphics, Inc. Sec. Litig.*, 183 F.3d 970, 986 (9th Cir. 1999). To determine whether sales
23 are suspicious or unusual, courts can look to whether the sales were consistent with the insider’s
24 prior trading history. Plaintiffs allege that prior to 2021 Tomasi had not sold any of his shares.
25 Although in some instances that might be unusual, Plaintiffs do not dispute that Tomasi made his
26 sales pursuant to a Rule 10b-5 trading plan. That fact cuts against a finding of scienter. *See, e.g.,*
27 *Metzler Inv. GBMH v. Corinthian Colls.*, 540 F.3d 1049, 1067 n. 11 (9th Cir. 2008); *In re Fastly,*
28 *Inc. Sec. Litig.*, No. 20-cv-06024-PJH, 2021 WL 5494249, at *11 (N.D. Cal. Nov. 23, 2021). The

1 timing of the sales also undermines any suspicious inference because they took place well before
2 Tomasi made the challenged statements. *See, e.g., Limantour v. Cray, Inc.*, 432 F. Supp. 2d 1129,
3 1151-52 (W.D. Wash. 2006) (“Defendants’ stock sales provide no evidence of scienter with regard
4 to allegedly false statements that were made after the stock sales ended.”). Finally, the record
5 shows that Tomasi held more stock at the end of the Class Period than he did at the beginning.

6 Looking at Plaintiffs’ allegations of scienter from a holistic perspective, the Court
7 concludes Plaintiffs have failed to allege sufficient facts to show Tomasi’s statements were
8 deliberately reckless, which also weighs against granting them leave to amend. Accordingly, the
9 Court DENIES Plaintiff’s request to re-open the Lead Plaintiff selection process.

10 CONCLUSION

11 For the foregoing reasons, the Court GRANTS Defendants’ motion to dismiss the SAC.
12 The Court DENIES Plaintiffs’ request for leave to re-open the Lead Plaintiff selection process and
13 DISMISSES this case with prejudice. The Court shall issue a separate judgment, and the Clerk
14 shall close the file.

15 **IT IS SO ORDERED.**

16 Dated: December 6, 2022

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18 JEFFREY S. WHITE
19 United States District Judge
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